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EXAMINER

SHEINBERG, MONIKA B

ART UNIT PAPER NUMBER

1631

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16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/281,990

Applicant(s)

ELLING ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21, 39-62, 67 and 69-90 is/are pending in the application.
- 4a) Of the above claim(s) 1-21, 39-62 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21, 39-62, 67 and 69-90 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

See the attached detailed Office action for a list of the certified copies (or not view).

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-849)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10, 11
- 4) ☐ Interview Summary (PTO-413) Paper No. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other \_\_\_\_\_

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**DETAILED ACTION*****Response to Amendment A***

Applicants' arguments, filed November 16, 2001, have been fully considered by they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

It is acknowledged that claims 22-38, 63-66, and 68 are canceled and claims 69-90 are new. Claims 1-21, 39-62, 67 and 69-90 are pending. Claims 1-21, 39-62 and 67 remain withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69-90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 75 is directed to the use of a subgraph isomorphism for an identification limitation. Claim 76 is directed to the use of a genetic algorithm for an identification limitation. The specification as originally filed does not teach or suggest the application of subgraph isomorphisms or genetic algorithms for the comparison of molecular structures. The identification limitation is not recited. Thus claims 75 and 76 are considered to be directed to subject matter not recited in the specification. Claims 77 and 78 are directed to a combination of molecular features set. The specification as originally filed does not teach or suggest the molecular feature set to be limited to continuous molecular structures or non-continuous combinations of molecular features as recited. Thus claims 77 and 78 are also considered to be directed to subject matter not recited in the specification. Applicant's arguments, filed November 16, 2001, have been fully considered by they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

requested to point to basis in the specification by page and line number for the limitations in claims 75-78.

Claims 69-90 have recast the previous claims by changing the term “pharmacophore” to “molecular feature set”. The specification does not disclose the specific language of the two terms being equivalent. The interpretation of a molecular feature set is much broader than that of a pharmacophore. In addition a “molecular feature set” is not a well-known term in the art. The specification does not clearly disclose the metes and bounds of a pharmacophore or a molecular feature set as claimed in order to determine them equivalent. Applicant is requested to point to basis in the specification by page and line number that describes the terms being set to be equivalent.

Claims 69-90 have recast the previous claims by changing the term “producing” to “identifying”. The parameters of the two words are different in that identifying simply pinpoints or distinguishes the object of the matter, while producing is an active term that makes or generates a product; in this case specific to pharmaceutical needs. Applicant is requested to point to basis in the specification by page and line number that describes the terms being set to be equivalent. The extent of what the pharmacophore/molecular feature set is based upon in terms of the instant invention remains unclear.

~~The following is a quotation of the second paragraph of 35 U.S.C. 112:~~

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

As necessitated by amendment, claims 69-90, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 69, 72, 83, 84, and 90 are vague and indefinite due to the lack of clarity in the use

assay determining the given activity or represent the assumption of the given activity. Claims 70, 71, 73-82, and 85-89, which are dependent from claims 69, 72, 83, 84, and 90, are also rendered vague and indefinite.

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Claim 71, 86, and 87 are vague and indefinite due to the acronym "SOM" used throughout these claims. The abbreviation lacks clarity in its exact meaning, and can be interpreted in many ways.

Claims 72 and 73 are vague and indefinite due to the use of the term "in response to" in line 4 of both claims. It is unclear what exactly is being responded to.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 22-38, 63-66, and 68 under 35 U.S.C. 102(b) as being anticipated by Hibert et al. (*J. Med. Chem.*, 1988) is hereby withdrawn and has not been applied to the new claims 69-90 in view of applicant's arguments.

Claims 69, 70, 72-74, 79-84 and 88-90 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al (*J. Chem. Inf. Comput. Sci.*, 1998).

Chen et al teaches a computerized method and system of identifying a set or group of molecules with particular features "to reflect a component of a pharmacophore model" (p. 1055, 2<sup>nd</sup> column, 2 paragraph) by the use of atom pair descriptors to describe each compound (p. 1056, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph) as recited in claim 69, 83, 84 and 90. The description of every molecule contains a "text explanation for each descriptor and a binary file containing a record for

tree and further separation and visualization output (claim 89) of the key structural features for particular active nodes are done by the SYBL program package with DISCO pharmacophore mapping module (p. 1058, 1<sup>st</sup> column, last paragraph). The model-derived pharmacophore-related

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72) and the predetermined group percentage (claim 73) containing a particular feature is demonstrated by the reference in that each compound in the group contains the feature, just as 100% of each group does. Due to the SAR program clustering per descriptor, the plurality of identification of a plurality of sets as recited in claim 79 is demonstrated by the reference. The maximum common substructure recited in claim 74 and 83, is only representative of that which is "likely to be responsible" (specification, p. 14, line 13) for the compound's activity. Thus the identification of the active substructure/feature of a compound is encompassed by a maximum common substructure within the group it is placed. As a computerized method, the computer readable mediums (claims 81 and 88) and computers (claims 82 and 89) of the system are inherent to the method. Thus Chen et al anticipates the instant claims.

Claims 69, 70, 72-74, 79-84 and 88-90 under 35 U.S.C. 102(b) as being anticipated by Brown et al. (*J. Med. Chem.*, 1988).

Brown et al teaches computerized structure-based clustering methods that screen or compare molecules to a "fragment dictionary" (p. 573, 1<sup>st</sup> column, 3<sup>rd</sup> paragraph), structural key descriptors, such as "MACCs substructure search system". MACCs along with SSKeys characterizes each structure as a bit-string that indicates the presence or absence of each key (8<sup>th</sup> paragraph) in addition to the number of key occurrences. This allows for the identification of a maximum common substructure (claims 72 and 83) upon noting the fragment with the greatest number of occurrences. Upon characterization of the structures, coefficients such as similarity and dissimilarity based on their physiochemical or biological property attributes (p. 572, columns 1-2) are analyzed for their particular activity/attribute. Thus Brown et al anticipates the limitations of claims 69, 70, 74, 79-83. The predetermined group number (claim 72) and the predetermined group percentage (claim 73) containing a particular feature is demonstrated by the reference in that each compound in the group contains the feature, just as 100% of each group does. Due to the SAR program clustering per descriptor, the plurality of identification of a plurality of sets as recited in claim 79 is demonstrated by the reference on pages 576-577, column 1, 3<sup>rd</sup> paragraph. Within the molecular feature set or activity cluster identified, the activity is further examined to "determine the degree of separation from one another" placed, for example, in an "active cluster subset" (p. 577, column 1, 3<sup>rd</sup> paragraph). As a computerized method, the computer readable medium,

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(claims 81 and 88) and computers (claims 82 and 89) of the system are inherent to the method. Thus Brown et al anticipates the instant claims.

### ***Information Disclosure Statement***

The websites listed on the information disclosure statement filed July 12, 1999, remain lined through and have not been considered. The print-out date is not when the information became available to the public. See 37 CFR 1.98.

The International Search Report of the information disclosure statement filed August 15, 2001, is lined through and will not be printed.

The websites listed on the information disclosure statement filed August 30, 2001, are lined through and have not been considered; the print-out date does not qualify as a publication date. The reference, Djoko et al (1995) is lined through because the reference is incomplete; all the figures are missing. Thus the information referred to therein has not been considered as to the merits.

### ***Conclusion***

No claim is allowed.

### ***Inquiries***

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993).

For inquiries, contact the examiner assigned to this application. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 31, 2002

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